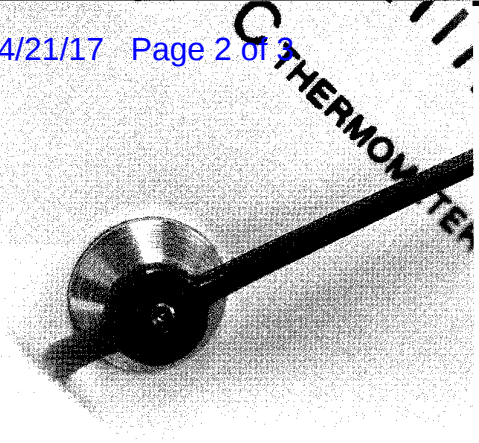
EXHIBIT 46

ICT INFECTION CONTROL TODAY



Forced-Air Warming:

An Effective Tool in Fighting SSI

IPs Asked to Weigh in on Warming Options

By Michelle Hulse Stevens, MD

Infection prevention and control departments have responsibility and oversight for implementing and monitoring strategies that help reduce infection risk throughout healthcare facilities. Infection preventionists are often asked to weigh in on strategies that are unfamiliar to them. In the perioperative setting, a proven and effective approach in helping fight surgical site infections is maintaining normothermia.

The benefits of normothermia maintenance are well known among anesthesia professionals, who are primarily responsible for patient temperature, but most infection preventionists are likely less familiar with the importance of normothermia and the tools that help achieve this goal. Clear understanding of normothermia practices is critical as broadened patient warming modalities enter hospitals and they are asked to make decisions regarding these options.

How Normothermia Contributes to SSI Reduction

Unintended or inadvertent hypothermia, defined as any core temperature of less than 36°C (96.8°F), is a frequent, preventable complication of surgery.[1] It is estimated that inadvertent perioperative hypothermia occurs in more than 50 percent of all U.S. surgical patients, even in those undergoing short procedures (one to one-and-a-half hours).[2]

Studies of the impact of hypothermia on the incidence of wound infection have shown that the hypothermic patient is at an appreciably greater risk for wound infection than a normothermic patient.[3] Intraoperative hypothermia triggers thermoregulatory vasoconstriction, decreasing the partial pressure of oxygen in the tissues, thereby lowering resistance to infection.[1] A reduction in core temperature of 1.9°C has been shown to triple the occurrence of surgical wound infections after colon resection and to increase length of hospital stays by 20 percent.[4]

Why Warming is an Increasingly "Hot" Topic

Numerous healthcare improvement initiatives around the world have identified normothermia maintenance as a key contributor to SSI reduction. For example, one commonly known practice bundle for the OR is CATS—Clipping (vs. shaving); Antibiotics (appropriate administration); Temperature (normothermia); Sugar (glucose control). The Centers for Medicare and Medicaid Services also has implemented a normothermia measure – SCIP-Infection-10.

The SCIP-Infection-10 measure applies to all patients regardless of age undergoing surgical procedures under general or neuraxial anesthesia one hour or longer, and measures the proportion of patients for whom either active warming was used intraoperatively or who had at least one body temperature equal to or greater than 96.8°F (36.0°C) recorded within the 30 minutes immediately prior to or the 15 minutes immediately after anesthesia end time.

Warming Technologies: An Overview

As consultants to the various areas of the healthcare system it is important for infection preventionists to familiarize themselves with the facts and supporting evidence regarding methods of warming.

Forced-air warming (or convective warming), and conductive warming modalities are the two primary methods of patient warming in the U.S., but they warm in very different ways. Forced-air warming utilizes the properties of convection and radiation. Heat transfer results from the movement of warm air across the surface of the patient's skin, which allows forced-air blankets to transfer more heat at a lower temperature.

As its name implies, conductive warming uses the properties of conduction and radiation to warm, with the heat from the mattress or over-the-body device being transferred to the body where there is direct surface-to-surface contact, most prominently at the body's natural pressure points.

For more than 20 years, forced-air warming—a technology found in more than 80 percent of U.S. hospitals—has been regarded as the standard of care in preventing the serious consequences of unintentional hypothermia.[5-9] Approximately 72,000 patients around the world are warmed each day using forced-air warming to maintain normothermia to help prevent SSIs and other serious complications of unintended hypothermia, including increased blood loss,[10-12] morbid myocardial events,[13] and reduced resistance to surgical wound infections.[1]

Comparative efforts between forced-air warming and other modalities have long occurred—and those comparisons continue today. Research presented as recently as October at the 2010 American Society of Anesthesiologists (ASA) annual meeting showed that Bair Hugger® forced-air warming therapy warmed patients significantly better than conductive resistive electric-type blankets and mattresses.[14-15]

- The results of one clinical trial showed that a Full Body Bair Hugger blanket re-warmed patients two times faster than a resistive electric full body blanket.[14] This study also showed that even after five hours of warming, the patients warmed with the resistive electric blanket did not achieve a normothermic temperature.[14]
- In another recent study, the Bair Hugger Full Access Underbody blanket was found to be significantly better in reducing post-bypass temperature afterdrop than a resistive heating mattress.[15]

The benefits of maintaining normothermia, of course, only come with a modality's effectiveness in achieving normothermia. Maintaining normothermia with forced-air warming has been demonstrated to reduce costly and serious complications associated with inadvertent hypothermia, including SSIs.

Clarity Regarding Forced-air Warming

Given the way forced-air warming systems work, by moving warm air gently across the surface of a patient's skin, the question of whether this disturbs protective airflow measures such as positive pressure or laminar airflow in the operating room resulting is airborne contaminants at the surgical site has arisen. Five independent studies have examined whether or not forced-air warming contributes to bacterial

contamination in laminar or standard airflow operating rooms,[16-20] none of which found an increase in bacterial counts from forced-air. These studies and those conducted by a number of other independent investigators have addressed this potential adverse effect and have not found evidence that supports an increased risk of infection at the surgical site related to the use of forced air warming.

- Research by Huang shows that forced-air warming actually decreases the bacterial count at the surgical site.[16]
- Hall and colleagues, and Zink and Iaizzo, tested the Bair Hugger forced-air warming system and showed no difference in microbial contamination of the simulated surgical site between warmed or unwarmed subjects.[17-18] These findings are logical because the Bair Hugger system draws in operating room air that is already filtered, filters it again, and delivers it to non-sterile portions of the patient's body, which have been carefully draped and isolated from the sterile field.
- The findings of Dirkes and colleagues showed that forced-air warming systems with filters ranging in size from 0.2 to 5.0 µm were able to completely exclude beta hemolytic Streptococcus from the airstream.[19] All Bair Hugger filters have a pore size of 0.2 µm, which far exceeds the level of room air filtration recommended by ASHRAE in a standard operating room.[21-22]
- Moretti et al examined the use of the Bair Hugger forced-air warming system in orthopedic surgery to assess the risk of contamination of the surgical site. The study quantified bacteria levels in different zones around the operating table and on the body's surface, both during surgery and in an empty OR, with and without the Bair Hugger system in use. Over the course of 30 total non-cemented hip implants, researchers found no real risk of nosocomial infections.[20]

In addition, in creating its Inadvertent Perioperative Hypothermia Guideline, the U.K.'s National Institute for Health and Clinical Excellence conducted a review of existing warming technologies. As part of its review, the Guideline Development Group (GDG) specifically explored potential adverse effects arising from various kinds of warming devices used for the prevention or treatment of inadvertent hypothermia. In section 10.4 of the full guideline published in 2008, the GDG examined research related to forced-air warming and the risk of infection. They did not find evidence indicating that properly used forced-air warming systems increased the risk of surgical site infection.[23]

Extensive Clinical Use, Extensive Evidence Base

Normothermia maintenance—and in particular, the use of forced-air warming—has been identified as a key surgical site infection reduction tool in quality initiatives and healthcare professional practice guidelines. It is essential that infection prevention professionals understand that forced-air warming use does not pose an infection risk. This is most important because of its potential positive impact on patient care. ICT

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